

Attorney Docket No.: T3106(C)
Serial No.: 10/583,233
Filed: January 17, 2008
Confirmation No.: 8248

REMARKS

Claims 4-5 and 19 have been cancelled without prejudice with Applicants reserving the right to file one or more continuation applications directed thereto. Claim 6 and 7 have been amended to change their dependency from claim 4 to claim 18.

Pursuant to the Office Action of February 2, 2011, claims 4-7 and 16 were rejected under 35 U.S.C. § 112 as non-enabling. Such rejection is rendered moot by the subject amendment. Claim 18 stands rejected under 35 U.S.C 103 over Majeed et al. (US2004/0121031). Respectfully, this rejection is traversed.

Skin appearance can be impacted by psychological stress. The instant inventors have developed an in-vitro model system that mimics the effects of chronic stress on skin, in particular **chronic** stress associated with the production of glucocorticoids, as well as the increased sensitivity to **acute** stress that such glucocorticoids engender. Using this model the instant inventors have found that **chronically stressed cells have a reduced ability to express certain proteins**. The inventors have also found that the increased sensitivity to acute stress that occurs in chronically stressed cells leads to **an increase in expression of proteins** involved in the skin inflammatory response. With these findings the inventors developed an assay method for identifying a first substance capable of helping the skin cope with **the inflammatory responses to acute stress** and a second substance capable of inhibiting glucocorticoid production associated with **chronic** stress.

Amended claim 18 identifies a first substance that is selected from a Markush group of ginsenoside Rb2, ginsenoside RC, curcumin, 22-)H-cholesterol, ciltitazone,

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mevinolin, commipheric acid, okadaic acid and mixtures thereof. As demonstrated by the data reported in Table 2 of the application, each of the eight materials individually named in the Makush group was shown to be effective in inhibiting the synthesis of ICAM-1, (Intra Cellular Adhesion Molecule 1, a marker of inflammatory status generated in response to acute stress in chronically stressed human umbilical vein endothelial cells).

The “second substance” identified by claim 18 is selected from a Markush group of materials identified as wolfberry extract, shiitake extract, activin, ginseng Rbl, ginseng Rc, curcumin, cigitazone, commipheric acid, boswellia extract and mixtures thereof. Each of these nine individually named materials was reported to inhibit the effects of glucocorticoid on levels of MMP-1 and procollagen expression on human dermal fibroblast cells. That is to say, the materials were found to inhibit glucocorticoid suppression of proteins associated with matrix degradation and matrix synthesis, processes needed to repair and maintain skin.

In the method described by claim 18, the administered composition comprises first and second substances that have been demonstrated by the instant data to provide benefits, when tested on human cells, in terms of inhibiting glucocorticoid suppression of proteins associated with skin repair and/or inhibiting the synthesis of proteins associated with stress induced inflammation.

Majeed et al., is directed to the use of glabridin (or liquorice extract, said to be rich in glabridin) as a metalloprotease or hyaluronidase inhibiting component in formulations for oral or topical use. In particular, glabridin is said to be useful in anti-aging and anti-wrinkle products as well as for use in products for treating diaper rash. The rejection is respectfully submitted to be rendered moot by the instant amendment. Moreover, it is respectfully submitted that there is nothing in the citation

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that discloses or suggests a composition comprising the instant combination of first and second substances or the administration of such a composition in a method of reducing the effects of neuroendocrine-mediated-psychologically-induced stress as required by claim 18.

In light of the above amendments and remarks, reconsideration and allowance of the subject claims is respectfully requested.

If a telephone conversation would be of assistance in advancing the prosecution of the present application, applicants' undersigned attorney kindly requests the Examiner to telephone at the number provided.

Respectfully submitted,

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